CLINICAL PRACTICE

ALERT

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Family PACT
Planning • Access • Care • Treatment
OFFICE OF FAMILY PLANNING
CALIFORNIA DEPARTMENT OF HEALTH SERVICES

Depo-Provera and Bone Density

In November 2004 the FDA required that the package labeling of DMPA Contraceptive Injection (Depo-Provera®) include information regarding loss of bone mineral density while using this medication. In particular, it advised that "bone loss may be greater with increasing use and may not be completely reversible, and for that reason, DMPA should be used as a long term birth control method (e.g., longer than 2 years) only if other birth control methods are inadequate." The Family PACT Clinical Practice Committee and staff have considered this information and other medical studies in the formulation the following recommendations.

KEY RECOMMENDATIONS

- **The two year use threshold should be considered clinically, but it does not constitute an absolute contraindication to the ongoing use of DMPA.**
- **Bone mineral density screening should not be recommended to a client for the sole purpose of evaluating appropriateness of DMPA usage. BMD screening tests are not a benefit of the Family PACT program.**
- **The information contained in the patient package insert shall be provided to clients as part of the informed consent process.**
- **For women 40 years old and older, there may be insufficient time between the discontinuation of DMPA and menopause to permit the regaining of lost bone. For this reason, as a woman's age progresses, consideration should be given to the discontinuation of DMPA or offering low dose estrogen supplementation to offset the effect of DMPA on bone loss.**
- **All female clients should be encouraged to have adequate calcium intake, if necessary with calcium supplementation. However, there are no studies demonstrating that calcium supplementation may lessen the BMD changes from Depo-Provera.**

Questions and Answers

Do all women who use DMPA lose bone density?
Studies show that about one quarter of DMPA users have estrogen levels in the menopausal range. In addition, most, but not all studies show that groups of DMPA users lose about 7 percent of bone density while using DMPA. However, most women will regain lost bone within 2 years of discontinuing DMPA.

Should DMPA users take "breaks" from DMPA use in order to regain bone or at least slow its loss?
Insufficient data exist regarding the effect of intermittent DMPA on bone density, so this strategy cannot be recommended. However, if the client chooses this approach, she should be advised to use another contraceptive method when not using DMPA.

Will DMPA use in younger women affect attainment of their "peak" bone mineral density?
It is unknown if the use of DMPA during adolescence or early adulthood will reduce peak bone mass and increase the risk of osteoporotic fracture later in life. The amount of bone loss is about equal to that with pregnancy and lactation.

Do prior users of DMPA have increased fracture rates when they become menopausal?
No! One study of prior DMPA users shows that they have slightly lower bone density levels than never users, but the difference was so small that it was felt to be unlikely that this would affect fracture risk.

Why not perform a bone mineral density test (e.g., DEXA scan) in prospective DMPA users?
BMD tests are intended to evaluate the degree of bone loss in women who already have achieved peak bone density as a method predicting fracture risk. There are no studies that apply to the interpretation of BMD test scores in a way that is clinically useful in the evaluation of prospective or current DMPA users.

Resources

1. Cundy T, Ames R, Horne A, et al. A randomized controlled trial of estrogen replacement therapy in long-term users of depot medroxyprogesterone acetate. J Clin Endocrinol Metab. 2003 Jan; 88(1):78-81.
2 . Cromer BA, Lazebnik R, Rome E, Stager M, et al. Double-blinded randomized controlled trial of estrogen supplementation in adolescent girls who receive depot medroxyprogesterone acetate for contraception. Am J Obstet Gynecol. 2005 Jan; 192(1):42-7.
3. Scholes D, LaCroix AZ, Ichikawa LE, et al. Change in bone mineral density among adolescent women using and discontinuing depot medroxyprogesterone acetate contraception. Arch Pediatr Adolesc Med. 2005 Feb; 159(2):139-44.
4. Depo-Provera Full Prescribing Information: http:www.pfizer.com/download/uspi_depo_provera_contraceptive.pdf accessed June 27, 2005.
5. Banks E, Berrington A, Casabonne D. Overview of the relationship between use of progestogen-only contraceptives and bone mineral density. BJOG. 2001 Dec; 108(12):1214-21. Review.

Application of Family PACT STANDARDS

Family PACT services are for family planning reproductive health: family planning methods and selected related conditions together with client-centered education and counseling.

1. Informed Consent

- The information contained in the DMPA patient package insert shall be provided to clients as part of the informed consent process.

2. Access to Care

- DMPA, as well as all other family planning methods, must be available at no cost to all Family PACT clients.

3. Availability of Covered Services

- All female Family PACT clients must be offered DMPA contraceptive injections, and it must be provided on-site.

4. Scope of Clinical and Preventive Services

- As with other contraceptive methods, the provision of DMPA shall be consistent with information presented here, as well as recognized medical practice.

5. Education and Counseling Services

- All clients shall be provided with adequate information to make an informed choice about family planning methods including verbal and written description of contraceptive methods including effectiveness, duration, side effects, complications, medical indications and contraindications.

Program Policy

This alert provides an interpretation of the Family PACT Standards for integration of Depo-Provera and Bone Density into current practice: minimum service delivery requirements for DMPA services. Providers should refer to the Family PACT *Policies, Procedures and Billing Instructions* for the complete text of the Family PACT Standards, official administrative practices and billing information. For the purposes of this and other Family PACT Clinical Practice Alerts, the term "shall" indicates a program requirement; the term "should" is advisory and not required.